



## BENEFITS OF BEING A PUBLISHED AUTHOR

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### Establishes Yourself as a Subject Matter Content Expert

By demonstrating your expertise, you move into a select group; setting yourself apart from non published colleagues.

### Industry Best Practice

You are playing a role in helping advance the current state of industry best practice in your area of subject matter content expertise. You are making a difference.

### Builds Credibility and Name Recognition

Consulting and industry presentation opportunities may present themselves in the future.

### Tests Your Expertise Against Our Peer-Review Process

Your expertise is tested against our subject matter content experts opinions of your work. Can you produce excellence?

### Great Addition

In the event of a job search in the future, a value-added addition to your resume.

## AUTHOR GUIDELINES

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### Writing Style

Clear and concise. Easy to understand. Written for personnel who are responsible for implementing and managing FDA compliance initiatives. Focusing on your subject matter at all times is critical to communicating your thoughts in a logical and efficient manner. Every sentence needs to be able to stand on its own; contributing to help complete the objectives of the article.

### Summary Article Paragraph

For this most important paragraph, we need to CONVINCED the reader that this article is worth investing their time to read it. This paragraph should include specific learning objectives and scope of the article. We recommend writing this paragraph AFTER you have completed the article.



## Regulatory Foundation: FDA Regulations

This paragraph must answer the question of “why am I reading this article?” For example, “FDA regulations 21CFR require pharmaceutical manufacturers...” As our readers have job positions in Quality Assurance, Operations, Validation, Manufacturing, and Research & Development in FDA-regulated industries, we must discuss the regulatory issues that readers will have to consider in the first 3-4 paragraphs of the paper. This is the initial entry point in our article of introducing the reader to our industry’s primary body of knowledge: FDA regulations.

## Step-by-Step Approach for Executing FDA Compliance Initiatives

Authors need to describe in methodical detail a plan for executing FDA compliance initiatives. We subscribe to a “how to” instructional approach. Bullet points, lists, flowcharts of processes and appropriate explanations are recommended. Examples are crucial in explaining complex methodologies.

## Examples

Illustrate key points of our papers. This is an important element of our writing style. Examples help readers relate to critical areas of emphasis.

## If You Were Auditing...

In the pharmaceutical cGMP Subparts series we publish, at the end of each 21 CFR regulation, our author included hints and tips for “if you were auditing this section of the regulation...”. We believe readers would find this information beneficial, especially if you are discussing a specific regulation in-depth.

## Charts

Are helpful with explanations or comparisons, (i.e., regulations.) Our philosophy is to demonstrate, (i.e., flowcharts) as much as possible; explain with minimal text.

## Acronyms

Need to be defined and first initial capitalized. For example, “The Out-Of-Specification (OOS) investigation revealed...” The next time and every other time thereafter, it can simply be referred to as OOS.

## SOP, Protocol or Other Related Documents

These are always considered value-added information when they are included as an addendum to an article.

## Page Length

At the author’s discretion, however, we recommend that the length of the article be in the 10-12 double spaced page range.



## Definitions

We always include a list of definitions from accredited industry sources, including FDA, other regulatory bodies, ISO, ICH, and many more, in the publication.

## References

When we reference an FDA regulation, guidance document or other industry standard in the text of an article, we need to include it in our list of references. This is our industry's body of knowledge.

## PUBLICATION DATES & AUTHOR SUBMISSION DEADLINES

<b>January Edition</b>	Author submission deadline:	November 15th
<b>March Edition</b>	Author submission deadline:	January 15th
<b>May Edition</b>	Author submission deadline:	March 15th
<b>July Edition</b>	Author submission deadline:	May 15th
<b>September Edition</b>	Author submission deadline:	July 15th
<b>November Edition</b>	Author submission deadline:	September 15th

We look forward to working with you.

Sincerely,

Glenn Melvin  
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